

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

**Civil Action No. 3:16-
md-2738- MAS-RLS**

MDL No. 2738

THIS DOCUMENT RELATES TO

Bondurant v. Johnson & Johnson

No. 3:19-cv-14366-MAS-RLS

Gallardo v. Johnson & Johnson

No. 3:18-cv-10840-MAS-RLS

Judkins v. Johnson & Johnson

No. 3:19-cv-12430-MAS-RLS

**THE PLAINTIFFS' STEERING COMMITTEE'S
MEMORANDUM OF LAW IN RESPONSE AND OPPOSITION
TO DEFENDANTS JOHNSON & JOHNSON AND
LLT MANAGEMENT, LLC'S MOTION TO EXCLUDE THE
SPECIFIC CAUSATION OPINIONS OFFERED BY
DR. JUDITH WOLF**

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The Plaintiffs’ Steering Committee (“PSC”) submits this Memorandum of Law in response and opposition to *Defendants Johnson & Johnson and LLT Management, LLC’s Motion to Exclude the Specific Causation Opinions Offered by Dr. Judith Wolf* (ECF Doc. 33003) (“Motion”). For the foregoing reasons, this Court should deny Defendants’ Motion.

I. INTRODUCTION

The PSC has produced evidence and expert testimony from Dr. Judith Wolf, a gynecologic oncologist, that exposure to Johnson’s *Baby Powder* and *Shower-to-Shower* (collectively “Talcum Powder Products”) are capable of causing ovarian cancer in plaintiffs Linda Bondurant, Anna Gallardo and Carter Judkins. In reaching her opinions she applied reliable methodology. Accordingly, the Defendants’ Motion to Exclude Dr. Wolf must be denied.

To be clear, the question at this time is not whether Dr. Wolf is right in her conclusions, but rather whether she is qualified to offer her opinions, and whether she applied reliable methodologies in reaching her opinions so that they are admissible at trial.

With respect to qualifications, there is no question that Dr. Wolf is an expert in the field of gynecologic oncology. In fact, Defendants do not dispute that Dr. Wolf is qualified to offer an expert opinion in this matter. The only issue then is methodology. With respect to methodology, Dr. Wolf followed a rigorous and

accepted methodology in assessing and weighing the scientific evidence on causation in the same manner she uses in her professional work outside of litigation. These methods include employing the causation framework and considerations described by Sir Bradford Hill in his seminal 1965 address¹ (“Hill Principles”) and the principles of evidence-based medicine.

As set forth in the PSC’s Opposition to Defendants’ Motion to Exclude Plaintiffs’ Experts’ General Causation Opinions (“General Causation Response”), there are multiple robust lines of scientific evidence relevant to the causation question at issue here. This evidence includes both published, peer-reviewed epidemiological and non-epidemiologic studies. Notwithstanding Defendants’ protestations, the overwhelming majority of these observational studies, irrespective of study design or population studied, found a *positive association* (i.e., a hazard or odds ratio > 1) between increased risk of ovarian cancer and genital talcum powder use. Importantly, within the past three months, further confirmation of this association was reported by NIH researchers in one of the most comprehensive talcum powder studies to have ever been conducted, reaffirming the existence of a positive link between genital talc use and ovarian cancer.²

¹ Bradford Hill, A, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc’y Med. 295 (1965), attached as **Exhibit 1**.

² O’Brien, KM, Wentzensen N, et al., Intimate Care Products and Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis, J Clin Oncol 00:1-15(2024), attached as **Exhibit 2**.

In addition to this consistent, positive and largely undisputed epidemiologic research, the PSC's General Causation Response sets forth published biologic, mechanistic and other non-epidemiologic evidence to further support the conclusion that the observed association between talcum powder and ovarian cancer is indeed a *causal association*. In fact, within the past two months, the International Agency for Research on Cancer (IARC) classified talc as "probably carcinogenic to humans."³ IARC confirmed the classification of talc containing asbestos as a known human carcinogen that can cause ovarian cancer.⁴

With the score mounting against Defendants, they try a new tactic: they move the goal posts. Although their own expert, Dr. Michael Finan, recently stated in his expert report "[d]ifferential diagnosis is not used in medical practice to determine the cause of cancer,"⁵ Defendants attempt to change their own rules and argue that

³ IARC Working Group, Carcinogenicity of Talc and Acrylonitrile, *Lancet Oncol* (July 5, 2024), attached as **Exhibit 3**.

⁴ IARC Monographs evaluate the carcinogenicity of talc and acrylonitrile, Questions & Answers and Press Release, Talc and Acrylonitrile (July 5, 2024), at 4-5, 12-13 ("There were numerous cancer studies in humans that consistently showed an increase in the incidence of ovarian cancer among women reporting use of body powder in the perineal region. However, the Working Group concluded that a causal association could not be fully established because the increase could potentially be explained by contamination of the talc with asbestos (which has been documented) or by biases arising from the studies' methodology. . . . The Working Group also noted that contamination of talc products with asbestos has been documented and that industry standards used to assess talc in cosmetic and pharmaceutical products have often not been sufficiently sensitive to rule out contamination with asbestos. . . . "Talc containing asbestos" remains a part of the definition of asbestos (classified as *carcinogenic to humans*, Group 1, by the *IARC Monographs* programme in 2009 in Volume 100C) and was not included in the present evaluation (Volume 136). There is *sufficient* evidence that asbestos causes mesothelioma and cancers of the lung, larynx, and ovary in humans."), attached as **Exhibit 4**.

⁵ Expert Report of Michael A. Finan, MD, May 28, 2024, at 65, attached as **Exhibit 5**.

Dr. Wolf's opinions should be excluded because she did not properly conduct a differential diagnosis. Consistent with 3rd Circuit case law, Dr. Wolf did in fact conduct a differential diagnosis. She thoroughly considered the plaintiff's medical history and exposure to talcum powder, then systematically ruled in and ruled out all potential causes of her ovarian cancer. She ultimately concluded that the genital use of talcum powder was a substantial contributing cause of ovarian cancer in these three plaintiffs.

In seeking to strike Dr. Wolf's opinions, Defendants devised a methodologic challenge when they actually disagree with her case-specific conclusions, conduct contrary to the mandate of *Daubert* and its progeny. Of course, a "battle of the experts" does not provide an appropriate *Daubert*-related basis for excluding an expert's opinion that is based on sound scientific methodology.⁶ Any differences in

⁶ See *S.E.C. v. Lucent Techs., Inc.*, 610 F. Supp. 2d 342, 351 (D.N.J. 2009) (quoting *Oddi v. Ford Motor Co.*, 234 F.3d 136, 146 (3d Cir. 2000); *Dzielak v. Whirlpool Corp.*, 2017 WL 1034197, at *26 (D.N.J. Mar. 17, 2017); *Lansford-Coaldale Joint Water Auth. v. Tonolli Corp.*, 4 F.3d 1209, 1216 (3d Cir. 1993) ("[I]n a battle of the experts, the factfinder 'decide[s] the victor.'" (alteration in original) (quoting *Mendes-Silva v. United States*, 980 F.2d 1482, 1487 (D.C. Cir. 1993); *In re Biogen '755 Patent Litig.*, 2018 WL 3586271, at *11 (D.N.J. July 26, 2018); *Lanzilotti by Lanzilotti v. Merrell Dow Pharm. Inc.*, 1986 WL 7832, at *3 (E.D. Pa. July 10, 1986) (the experts for both sides differed as to what interpretations should be given to various data. "The case was thus a classic battle of the experts, a battle in which the jury must decide the victor."); *In re Gabapentin Patent Litig.*, 2011 WL 12516763, at *10 (D.N.J. Apr. 8, 2011) (concluding that defendants' critiques of plaintiffs' experts' methodology and inconsistent conclusions presented "a battle of the experts, and both sides will be permitted to present expert testimony on these issues and to cross-examine the other side's expert witnesses.")).

expert opinions should be explored on cross-examination and not excluded as unreliable.

Defendants' Motion to Exclude Dr. Wolf should be denied for the following reasons:

1. Dr. Wolf conducted a case-specific analysis of each plaintiff. She methodically considered the case-specific facts of each case, as well as each known risk factor and protective factor for ovarian cancer, ruling in and ruling out factors relevant to each plaintiff. This methodology is precisely the differential diagnosis Defendants argue she did not conduct.
2. Dr. John Godleski's opinions are not dispositive to the admission of Dr. Wolf's opinions.

At best, Defendants' challenges to differences in the interpretation of scientific evidence raise nothing more than jury-appropriate questions. Accordingly, Defendants' Motion must fail.

II. DR. WOLF'S BACKGROUND AND METHODOLOGY

Dr. Wolf is a board certified gynecologic oncologist, a physician specializing in the care of women with cancer, with more than thirty years' experience.⁷ She was a professor at MD Anderson Cancer Center for more than 20 years, a clinical

⁷ Third Amended Expert Report of Judith Wolf, MD, May 28, 2024 ("Wolf Rep.") at 2 and Exhibit A (Wolf CV), attached as **Exhibit 6**.

researcher for more than 10 years, and the Chief Medical Officer for two diagnostic companies in the biomedical industry. She has published over 100 peer-reviewed manuscripts, served as principal investigator, co-investigator or collaborator on 11 research grants and numerous protocols, and she has presented at more than 50 conferences. She continues to practice medicine as a gynecologic oncologist, treating women with ovarian cancer and other gynecologic malignancies in numerous medical centers around the country.⁸

Dr. Wolf's methodology included a systemic review of the relevant literature, including peer-reviewed papers, original research, case-controlled studies, cohort studies, meta-analysis studies, and systemic analyses. Additionally, she reviewed relevant textbooks and sought additional materials as needed. She "approached this issue in a similar way and with the same rigor" she has employed in her "own professional practice, both clinically and in research."⁹ Grounded in 30+ years of knowledge and experience as a gynecologic oncologist, she "consider[ed] the reliability and validity of the medical and scientific literature, assessing the evidence according to the strengths and weaknesses of the study under review."¹⁰ Dr. Wolf formed her expert opinions "using a weight of the evidence methodology in the context of Bradford Hill concepts."¹¹ She concluded "to a reasonable degree of

⁸ *Id.*

⁹ *Id.* at 2.

¹⁰ *Id.* at 3.

¹¹ *Id.*

scientific and medical certainty that Johnson’s Baby Powder and Shower to Shower products cause epithelial ovarian cancer [EOC] in some women. The use of talcum powder products presents a significant risk factor for ovarian cancer in *all* women who use the products.”¹²

Importantly, the methodology employed by Dr. Wolf to opine on general causation was found to be reliable and admissible by this Court following an extensive Daubert process.¹³ Dr. Wolf then conducted a case-specific analysis for three bellwether plaintiffs in this litigation: Linda Bondurant, Anna Gallardo and Carter Judkins. In each case, she reviewed all the available medical records, deposition testimony, and Plaintiff Profile Form for each plaintiff, as well as Dr. John Godleski’s expert report for Ms. Gallardo and Ms. Judkins.¹⁴ She then considered all the relevant factors that could contribute to the development of the plaintiff’s ovarian cancer, forming a differential diagnosis.¹⁵

III. THE MEDICAL CONSENSUS: TALCUM POWDER IS A RISK FACTOR EPITHELIAL FOR OVARIAN CANCER

In formulating her case-specific opinions, Dr. Wolf considered known risk

¹²*Id.* at 22 (emphasis in original).

¹³ See *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prod. Liab. Litig.*, 509 F.Supp.3d 116 (D.N.J. 2020).

¹⁴ Second Amended Rule 26 Expert Report of Judith Wolf, MD – Bondurant (“2d Amd. Bondurant Rep.”), May 28, 2024, at 23, attached as **Exhibit 7**; Second Amended Rule 26 Expert Report of Judith Wolf, MD – Gallardo (“2d Amd. Gallardo Rep.”), May 28, 2024, at 22, attached as **Exhibit 8**; Second Amended Rule 26 Expert Report of Judy Wolf MD – Judkins (“2d Amd. Judkins Rep.”), May 28, 2024, at 23, attached as **Exhibit 9**.

¹⁵ 2d Amd. Bondurant Rep. at 24; 2d Amd. Gallardo Rep. at 23; 2d Amd. Judkins Rep. at 23.

factors and protective factors, ruling in and ruling out associated factors for each plaintiff.

A. The Clinical Definition Of “Risk Factor”

In clinical medicine, the term “risk factor” is often used to describe something that increases the chance of developing a disease.¹⁶ An “evidence-based medicine” approach for doctors is very similar to a Bradford-Hill analysis, as “medical decisions should be based on quality evidence.”¹⁷ Cause and risk factor are often used interchangeably, assuming there exists a plausible biological mechanism to explain the association.¹⁸ This methodology for determining cancer causality merges traditional epidemiology, molecular research, and public health decision-making.¹⁹ In addition to epidemiological studies reporting a consistent association of talcum powder use and the risk of ovarian cancer, there are numerous peer-reviewed medical

¹⁶ See National Cancer Institute, *NCI Dictionary of Cancer Terms*, available at <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/risk-factor>, attached as **Exhibit 10**.

¹⁷ Wendy R. Brewster, *Epidemiology of Commonly Used Statistical Terms and Analysis of Clinical Studies*, Clinical Gynecologic Oncology at 579-585 (9th ed. 2017), attached hereto as **Exhibit 11**.

¹⁸ See Deposition of Daniel L. Clarke-Pearson, M.D., February 4, 2019 at 80:3-5, 79:15-17 (“They’re virtually the same. A risk factor describes a cause. It does not affect every woman that has that risk factor.”), attached hereto as **Exhibit 12**; Wolf Rep. at 3 (“A causative risk factor is one that increases the chances of developing a disease by means of a known or predictable mechanism. In other words, it is more than a mere association.”).

¹⁹ Paolo Vineis, *et al.*, *Causality in Cancer Research: A Journey through Models in Molecular Epidemiology and Their Philosophical Interpretation*, 14 *Emerging Themes in Epidemiology* 7 (2017) (“[C]ausal reasoning is based on both ‘evidence of difference-making’ (e.g., associations) and on ‘evidence of underlying biological mechanisms.’ This is important not only to understand cancer etiology, but also to design public health policies that target the right *causal* factors at the macro- level.”), attached as **Exhibit 13**.

publications, particularly in recent years, describing and listing talcum powder use as a risk factor for epithelial ovarian cancer (EOC), thus incorporating mechanism. In addition to talcum powder and asbestos exposure, other risk factors that have been linked to EOC include increasing age, nulliparity, infertility, endometriosis, obesity, polycystic ovarian syndrome, use of an intrauterine device, history of pelvic inflammatory disease, and cigarette smoking (for mucinous carcinoma). Protective factors (*i.e.*, those factors associated with a decreased risk of EOC) include previous pregnancy, history of breastfeeding, oral contraceptives, and tubal ligation.²⁰

It is important to note that risk factors can interact with each other or act independently. They can act in a cumulative, additive, and/or synergistic fashion.²¹ Talcum powder usage is often referred to as a “lifestyle risk factor” and therefore, a modifiable and preventable cancer cause.

B. The Medical Literature Recognizes Talcum Powder as a Risk Factor for Epithelial Ovarian Cancer

There are multiple peer-reviewed publications that recognize the genital use of talcum powder as a risk factor for epithelial ovarian cancer. Some examples follow.

- **Hunn and Rodriguez (2012):** in a review article titled “Ovarian Cancer: Etiology, Risk Factors, and Epidemiology” include “perineal talc exposure” as an “inflammatory risk factor,” describing the

²⁰ See Wolf Rep. at 4.

²¹ Song Wu, *et al.*, *Evaluating Intrinsic and Non-Intrinsic Cancer Risk Factors*, 9 Nature Comm’n 3490 (2018) (“Non-intrinsic and intrinsic risk factors often do not act independently as we have highlighted, and the most likely scenario is that they cooperate to cause cancer”); attached as **Exhibit 14**.

“[e]vidence demonstrating an association between talc use and an increased risk of ovarian cancer suggests that environmental toxins can enter the lower genital tract and migrate upward through the uterus and fallopian tubes to enter the peritoneal cavity and act as ovarian carcinogens.”²² This article is cited by the National Cancer Institute in its Physician Data Query: Ovarian, Fallopian Tube, and Primary Peritoneal Cancers Prevention (PDQ®)—Health Professional Version: Who is at Risk?²³

- **Mallen *et al.* (2018):** in a review titled, “Risk Factors for Ovarian Carcinoma,” included in its risk factor chart genital powder use as a “Lifestyle Risk Factor” for all serous, endometrioid and clear cell carcinomas.²⁴
- **Park *et al.* (2018):** described the increased risk in the African-American population: “In particular, talc powder use is highly prevalent in the African-American community and has been found to be associated with increased risk of ovarian cancer in this and other studies.”²⁵
- In a textbook chapter titled Ovarian Cancer Prevention and Screening, the authors described talc use as a “lifestyle factor,” stating that the “[u]se of talc in the genital area has been consistently shown to increase the risk of OC and therefore is not recommended.”²⁶
- The Institute of Medicine (IOM) in the “state of the science” treatise on

²² Hunn J and Rodriguez G, Ovarian Cancer: Etiology, Risk Factors, and Epidemiology (2012), Clinical Ob Gyn 55:1 at 6, attached as **Exhibit 15**.

²³ National Cancer Institute, Ovarian, Fallopian Tube, and Primary Peritoneal Cancers Prevention (PDQ®)—Health Professional Version: Who is at Risk?, March 6, 2024, attached as **Exhibit 16**.

²⁴ Mallen A, Townsend M, *et al.*, Risk Factors for Ovarian Carcinoma, Hematol Oncol Clin N Am (2018) at 4, attached as **Exhibit 17**.

²⁵ Park H, Schildkraut J, *et al.*, Benign Gynecological Conditions are Associated with Ovarian Cancer Risk in African-American Women: a Case-Control Study, Cancer Causes & Control (2018) at 8, attached as **Exhibit 18** (noting “The risk associated with serous ovarian cancer in women with a history of multiple conditions was higher than individual associations observed in any one gynecologic condition. This observation may suggest a possible additive or synergistic effect on tumorigenesis influenced by the pro-inflammatory milieu from an increased burden in the number of benign conditions. Increased risk of serous carcinoma in women with other pro-inflammatory risk factors has been reported, *most notably in talc users.*”) (emphasis added).

²⁶ Eeles R, Berg C., *et al.*, *Cancer Prevention and Screening: Concepts, Principles and Controversies*, Chapter 23 at 337 (2018), attached as **Exhibit 19**.

ovarian cancer identified talc and asbestos as inflammatory factors associated with ovarian cancer in the biological plausibility section.²⁷

- **Phung, *et al.* (2022):** The Ovarian Cancer Association Consortium, a consortium composed of leading ovarian cancer researchers in the world, listed talcum powder use as a well-established risk factor for ovarian cancer.²⁸

1. Ovarian Cancer Subtypes

It is customary to refer to ovarian, fallopian tube, and primary peritoneal cancer as a single entity, distinguishing histologic subtypes only when appropriate. The epidemiological literature commonly does not distinguish between subtypes, nor do treatises by medical societies or governmental agencies (*e.g.*, IARC, Health Canada, FDA). For example, the National Cancer Institute (NCI) treats Ovarian, Fallopian Tube, and Primary Peritoneal Cancer as a single cancer, as does the American College of Obstetrics and Gynecology (ACOG). A recent review seminar published in the *Lancet* (2019), titled “Epithelial ovarian cancer” provides a further example. Although the distinct histological subtypes are discussed in this article, epithelial ovarian cancer is addressed as a whole, including risk factors.²⁹

Defendants argue that clear cell carcinoma – the subtype with which Ms.

²⁷ IOM Comm. On the State of the Science in Ovarian Cancer Research, *Ovarian Cancers: Evolving Paradigms in Research and Care* (2016) at 110, attached as **Exhibit 20**.

²⁸ Phung, MT, *et al.*, *Effects of risk factors for ovarian cancer in women with and without endometriosis*. *Fertility and Sterility*. Vol. 118, No. 5. 960-969 (2022), attached as **Exhibit 21**.

²⁹ Lheureux S, Gourley C, *et al.*, *Epithelial Ovarian Cancer*, *The Lancet* 393:1240–53 (2019), attached as **Exhibit 22**.

Bondurant was diagnosed – shows no association with talcum powder use.³⁰ That statement is simply untrue. Genital talcum powder use has been associated with at least a 24% statistically significant increased risk of invasive clear cell ovarian cancer (OR, 1.24; 95% CI, 1.01-1.52).³¹ Defendants’ longwinded argument disagreeing with this study and others like it simply poses a jury question.

IV. LEGAL ARGUMENT

A. Legal Standards For The Admissibility Of Expert Causation Opinions

The PSC incorporates the *Plaintiffs’ Steering Committee’s Brief Regarding the Rule 702 Standard* (hereinafter “*PSC’s Rule 702 Brief*”) and highlights the following important points of particular relevance to the outcome this motion:

First, Fed. R. Evid. 702 has “a liberal policy of admissibility.”³² Exclusion of expert testimony is only appropriate when such testimony qualifies as irrelevant or “junk science.”³³ Otherwise, the trial court should cede complex issues to the jury and rely on the traditional safeguards of the adversary system—active cross-

³⁰ Motion at 1.

³¹ Terry KL, Karageorgi S, et al., Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls, *Cancer Prev. Res.* 2013; 6:817, attached as **Exhibit 23**; *see also* Schildkraut, JM, et al. Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES). *Cancer Epidemiol Biomarkers Prev*; 25(10); 1411–7 (any genital use of powder and nonserous EOC OR 1.63 (1.04-2.55)), attached as **Exhibit 24**.

³² *Geiss v. Target Corp.*, 2013 WL 4675377, at *4 (D.N.J. Aug. 30, 2013) (citing, *inter alia*, *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

³³ *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596, 113 S. Ct. 2786 (1993).

examination, presentation of contrary and competing expert testimony—rather than exclude from juror scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.³⁴

Second, differing and competing expert opinions, precisely what Defendants have presented to the Court, are traditionally left for the jury. The *Daubert* analysis focuses on the methodology underlying an expert’s opinion, not the expert’s conclusions.³⁵ Therefore, the focus of admissibility under *Daubert* is the reliability of the experts’ methods, not their correctness.³⁶ The trial court is not empowered “to determine which of several competing scientific theories has the best province.”³⁷ As long as the expert’s testimony falls within “the range where experts may reasonably differ,” then it is up to the jury to decide among the competing views.³⁸

Third, causal inference is a matter of judgment about the totality of the scientific evidence. “Drawing causal inference . . . requires judgment and searching analysis based on biology, of why a factor or factors may be absent despite a causal

³⁴ *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999) (amended on other grounds).

³⁵ *Daubert*, 509 U.S. at 595.

³⁶ *Id.* at 585. *See also* *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 1969 (1988); Fed. R. Evid. 702.

³⁷ *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citations omitted).

³⁸ *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153, 119 S. Ct. 1167 (1999); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 2016 WL 4039286, at *2 (E.D. Pa. July 28, 2016) (“Fed. R. Evid. 702 and *Daubert* put their faith in an adversary system designed to expose flawed expertise.”); *United States v. Mitchell*, 365 F.3d 215, 244–45 (3d Cir. 2004) (citations omitted) (“As long as an expert’s scientific testimony rests upon ‘good grounds, based on what is known,’ it should be tested by the adversary process— competing expert testimony and active cross-examination . . .”).

relationship, and vice versa.”³⁹ As noted in the *Reference Manual on Scientific Evidence*: “Although the drawing of causal inference is informed by scientific expertise, it is not a determination that is made by using an algorithmic methodology.”⁴⁰ As this judgment is a scientific determination, it can evolve “as new evidence develops” because “the scientific enterprise must always remain open to reassessing the validity of past judgments.”⁴¹ The judgment of whether to draw a causal inference can lead to disagreement amongst experts in the field.⁴² In the end, deciding whether associations are causal typically is not a matter of statistics alone, but also rests on scientific judgment.”⁴³ Defendants’ brief is silent on this essential point.

Fourth, a causal inference requires an examination of the totality of the scientific evidence. “Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention.”⁴⁴ This is how science outside of the courtroom functions. There is

³⁹ *Reference Manual on Scientific Evidence*, Federal Judicial Center, Third Edition (2011) (“Ref. Man.”) at 600.

⁴⁰ *Id.*

⁴¹ *Id.* at 598.

⁴² See, e.g., *In re Neurontin Marketing, Sales Practices, and Products Liability Litigation*, 612 F. Supp. 2d 116, 149 (D.Mass. 2009) (causation supported by biologic plausibility notwithstanding the “robust debate in the scientific community” regarding the proposed mechanism); *Milward*, 639 F.3d at 18; *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 174 F. Supp. 3d 911 (D.S.C. 2016); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1833173, at *9 (N.D. Ill. May 8, 2017).

⁴³ *Ref. Man.* at 20, 21, 222, 553, 565, 591, 599 and 600.

⁴⁴ *Id.* at 19–20; see also *Milward*, 639 F.3d at 26 (reversing the district court’s exclusion of expert testimony based on an assessment of the contribution of individual studies and finding that the

simply no definitive checklist or magic formula for making scientific judgments. As explained in the *Reference Manual*:

It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine, the National Research Council, and the National Institute for Environmental Health Sciences) consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence. In applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed.⁴⁵

The Third Circuit, as well as numerous other courts, has endorsed an expert's use of the "weight of the evidence" approach to assessing the "totality" of evidence for evaluating causation.⁴⁶

Fifth, science does not demand certainty. Nor does the law. Under Third Circuit *Daubert* standards, the trial court should not impose "a standard of scientific certainty . . . beyond that which *Daubert* envisions."⁴⁷ Plaintiffs also are not required to present evidence that is conclusive or unequivocal. "[I]n epidemiology hardly any

"weight of the evidence" properly supported the expert's opinion).

⁴⁵ *Ref. Man.* at 600.

⁴⁶ See *In re Zolof (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796– 797 (3d Cir. 2017) (citing *Milward*, 639 F.3d at 17 ("[t]he court treated the separate evidentiary components of [the expert's] analysis atomistically, as though his ultimate opinion was independently supported by each."); see also *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 198 F. Supp. 3d 446, 458 (E.D. Pa. 2016); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003) (rejecting defense *Daubert* challenges which "isolate these sources [of evidence] rather than considering the whole").

⁴⁷ *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 86 (1st Cir. 1998).

study is ever conclusive, and we do not suggest that an expert must back his or her opinion with published studies that unequivocally support his or her conclusions.”⁴⁸ Science and medicine often do not lead to certainty and the law does not require certainty.⁴⁹

B. Defendants’ Motion Improperly Requests That the Court Weigh The Evidence On The Relationship Between Talcum Powder Products And Ovarian Cancer

In the context of a *Daubert* motion, the question before the Court is not whether the movant’s experts or the respondent’s experts are correct or even what conclusion the Court would come to if it were the trier of fact. The sole question is whether each challenged expert used a reliable methodology.⁵⁰ Defendants’ motion nevertheless attempts to convince the Court that it is “right” while disguising its arguments as a methodological challenge.

In seeking to exclude Dr. Wolf’s case-specific opinions, J&J has sought to pit its experts’ “conclusions” against Dr. Wolf’s “conclusions,” to inappropriately exclude the “flawed” opinions J&J does not agree with. The fact that experts reach different conclusions about a matter, however, is not a methodologic issue and is no

⁴⁸ *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007).

⁴⁹ *Milward*, 639 F.3d at 22 (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)).

⁵⁰ *See In re Testosterone*, 2017 WL 1833173, at *9 (“At this stage, it is not the Court’s role to choose between competing studies...the studies “merits and demerits...can be explored at trial.”) (citation omitted); *In re Roundup Prod. Liab. Litig.*, 2018 WL 3368534, at *2–3 (N.D. Cal. July 10, 2018) (“So long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge; instead the weaknesses in an unpersuasive expert opinion can be exposed at trial, through cross examination or testimony by opposing experts”).

basis for a *Daubert* challenge. Moreover, as set forth below, many of Defendants' conclusions are based on inaccurate and unsupported facts.

The *Reference Manual* notes that the question of causal inference is not subject to a mathematical or mechanical formula and a difference in opinion is simply not the basis to exclude a qualified experts' opinion.⁵¹ A causal inference requires an examination of the *totality of the scientific evidence*. When an issue involves a multitude of evidence, appropriate scientific methodology requires consideration of the cumulative effect of all of the scientific evidence and not only certain parts. "Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention."⁵²

As Leon Gordis, MD, an editor of the *Reference Manual* observed in his textbook *Epidemiology* (5th Ed):

Although it may be a desirable goal to place causal inferences on a firm quantitative and structural foundation, at present we do not have all of the information needed for doing so. [The Bradford Hill aspects] should therefore be considered to be only guidelines that can be of most value when coupled with reasoned judgment about the entire body of available evidence, in making decisions about causation.⁵³

Reasoned judgment and difference of opinion are part of the process. In his

⁵¹ *Ref. Man.* at 600 (rejecting an "algorithmic methodology" to determine causation).

⁵² *Ref. Man.* at 19–20.

⁵³ Leon Gordis, *Epidemiology* Chapter 14, at 260. (5th ed. 2013), attached as **Exhibit 25**.

Cancer Epidemiology textbook entitled *Risk Factors for Cancer In the Workplace*, the PSC's expert, Jack Siemiatycki, Ph.D, bluntly observed the simple truth: "Equally competent scientists, examining the same information, can arrive at different [causal] conclusions."⁵⁴

Defendants' motion does not describe either a true *methodologic* challenge or a legitimate contention that Dr. Wolf *refused* to consider relevant evidence (*e.g.*, *In Re Zolof*). That Dr. Wolf's case-specific opinions may be different than those of Defendants' experts simply presents a jury question. The real question is whether there is *any* evidence that Dr. Wolf engaged in unreliable methodologies in reaching her opinions. As set forth below, there is none.

C. In Dr. Wolf's Case-Specific Analyses, She Methodically Considered All Relevant Factors, Ruling In And Ruling Out Factors With Regards To Each Plaintiff.

Differential diagnosis is a method used by medical experts to determine the cause of a plaintiff's injury by systematically ruling out alternative causes.⁵⁵ The Third Circuit has held that differential diagnosis is a reliable method for determining causation in product liability cases.⁵⁶

"The first step in properly conducting a differential diagnosis is for the expert to 'rule[] in' all plausible causes for the patient's condition by compiling a

⁵⁴ Jack Siemiatycki, *Risk Factors for Cancer In the Workplace*, at 298, attached as **Exhibit 26**.

⁵⁵ *Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 156 (3d Cir. 1999) (allowing the expert's opinions based on a differential diagnosis).

⁵⁶ *Id.*

comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.”⁵⁷ An examination of the plaintiff’s medical records is a reliable method.⁵⁸ “At this stage, the issue is which of the competing causes are *generally* capable of causing the patient's symptoms or mortality.”⁵⁹

“Second, after the expert ‘rules in’ plausible causes, the expert then must ‘rule out’ those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case.”⁶⁰ “A medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness.”⁶¹ “[T]hat is a more stringent standard for a medical expert’s differential diagnosis than is required under Rule 702.”⁶²

[T]o require the experts to rule out categorically all other possible causes for an injury would mean that few experts would ever be able to testify....

... Obvious alternative causes need to be ruled out. All possible causes, however, cannot be and need not be eliminated before an expert's testimony will be admitted..⁶³

⁵⁷ *Creanga v. Jardal*, 886 A.2d 633, 639 (N.J. 2005) (internal citations omitted) (finding the expert’s differential diagnosis was properly conducted and therefore admissible).

⁵⁸ *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 807 (3d Cir. 1997) (allowing expert’s testimony based on differential diagnosis).

⁵⁹ *Creanga*, 886 A.2d at 639 (internal citations omitted) (*emphasis in original*).

⁶⁰ *Id.* (internal citations omitted).

⁶¹ *Heller*, 167 F.3d at 156.

⁶² *Id.*

⁶³ *Id.*, citing Daniel J. Capra, *The Daubert Puzzle*, 32 Ga.L.Rev. 699, 728 (1998).

Only “where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.”⁶⁴ The rule requires only that the expert should “employ[] sufficient diagnostic techniques to have good grounds for his or her conclusion.”⁶⁵ The “hallmark” of differential diagnosis is for the expert to identify several possible causes, consider the alternatives, and rule them out to reach her conclusion with a reasonable degree of medical certainty.⁶⁶

The methodology described above is precisely the methodology Dr. Wolf used in her case-specific analyses. For each plaintiff, she first describes the materials she reviewed: all the available medical records, deposition testimony, Plaintiff Profile Form and, where available, Dr. Godleski’s expert report or pathological findings.⁶⁷ She then spends several pages for each plaintiff describing in detail her medical history, cancer diagnosis, cancer treatment, and related injuries. Dr. Wolf then describes her differential diagnosis for each plaintiff, the first step of which is ruling in all plausible causes for the plaintiff’s condition by compiling a comprehensive list of known risk factors and protective factors associated with ovarian cancer. She then addresses each factor, ruling out the factors that did not

⁶⁴ *Heller*, 167 F.3d at 156.

⁶⁵ *Id.*

⁶⁶ *Poust v. Huntleigh Healthcare*, 998 F.Supp. 478, 497 (D.N.J. 1998) (admitting expert’s testimony over objections that he failed to consider every possible cause).

⁶⁷ 2d Amd. Bondurant Rep. at 23; 2d Amd. Gallardo Rep. at 22; 2d Amd. Judkins Rep. at 22.

cause the plaintiff's ovarian cancer by engaging in a process of elimination, eliminating risk factors and protective factors that did not apply. Through a continuing examination of the evidence, Dr. Wolf reaches her conclusion as to the most likely cause of the findings in that particular case, to a reasonable degree of medical and scientific certainty.

To be even more specific, as to each plaintiff, Dr. Wolf asked the following questions: Did the plaintiff have ovarian cancer? Was the histologic subtype consistent with those associated with talcum powder products? Did the plaintiff have a history of sufficient perineal use of talcum-containing products? Was the timing of her diagnosis consistent with a talcum powder effect? Were there talc particles present in the tissues analyzed, lending support to causation?

As noted above, Dr. Wolf also examined the plaintiff's medical history to determine whether the plaintiff had protective factors asking the following question -- Were there protective factors present and, if so, what was their contribution to the development of ovarian cancer? She assessed whether the plaintiff had pregnancies, used oral contraceptives, had a tubal ligation or had undergone a hysterectomy. Importantly, she determined whether the plaintiff had other risk factors for ovarian cancer besides genital talc use, such as: genetic risk factors; family history; increasing age; nulliparity and infertility; endometriosis; polycystic ovarian syndrome; obesity; use of an intrauterine device; history of pelvic inflammatory

disease; and cigarette smoking.⁶⁸

In spite of these detailed analyses, Defendants suggest that Dr. Wolf did not adequately consider each plaintiff's medical history. To the contrary, in addition to her case-specific reports as quoted above, Dr. Wolf specifically addressed each potential risk factor in her depositions. Oddly enough, Defendants cite much of Dr. Wolf's deposition testimony in support of their argument that she did not consider these factors.

Ms. Bondurant-

[REDACTED]⁶⁹ Dr. Wolf testified as follows:

- [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] 72

⁶⁸ 2d Amd. Bondurant Rep. at 24-25; 2d Amd. Bondurant Rep. at 24-25; 2d Amd. Judkins Rep. at 24-25.

⁶⁹ Motion at 19-23.

⁷⁰ Dep. of Judith Wolf, M.D., Sept. 14, 2021, at 573:2-7, attached as **Exhibit 27**.

⁷¹ *Id.* at 438:8-17.

⁷² *Id.* at 438:1-3.

- [REDACTED]
[REDACTED]
[REDACTED]⁷³

Ms. Gallardo – [REDACTED]

[REDACTED]. Dr. Wolf testified as follows:

- [REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

Ms. Judkins – [REDACTED]

[REDACTED] Dr. Wolf testified as follows:

- [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]⁷⁸

Given the detailed analysis employed by Dr. Wolf with regard to each plaintiff, there is no basis for Defendants’ claims (1) that she did not “rule in” talc, when she addressed talc directly in questions 2-5 of each differential diagnosis; or

⁷³ *Id.* at 577:22-25; 2d Amd. Bondurant Rep. at 25.

⁷⁴ Dep. of Judith Wolf, M.D., Sept. 13, 2021, at 326:4-7, attached as **Exhibit 28**.

⁷⁵ *Id.* at 327:16-18.

⁷⁶ Motion at 23-25.

⁷⁷ Dep. of Judith Wolf, M.D., Sept. 14, 2021, at 577:14-17.

⁷⁸ *Id.* at 579:7-12.

(2) that she did not “rule out” other potential causes of the plaintiffs’ cancers, when she specifically lists each known risk factor and whether or not each applies to each plaintiff. As explained by Dr. Wolf, cancer is a multifactorial disease; a single risk factor may be one of the factors that leads to ovarian cancer, but in and of itself does not necessarily cause ovarian cancer.⁷⁹ Dr. Wolf identified several possible causes, considered the alternatives, including the fact their cancers may be idiopathic, and ruled out those factors to reach her conclusion with a reasonable degree of medical certainty.⁸⁰ Based on New Jersey and Third Circuit case law, her methodologic approach meets the requirements of admissibility under Rule 702.

Defendants may not agree with Dr. Wolf’s conclusions, but their arguments go to the weight of her opinions, not their admissibility. As stated by the Third Circuit, “we emphasized that the district court should take care not to mistake credibility questions for admissibility questions. If the medical expert’s opinion on causation has a factual basis and supporting scientific theory that is reliable, it should be admitted.”⁸¹ As detailed above, Dr. Wolf’s opinion has a factual basis and reliable, supporting scientific theory; thus, it should be admitted. Defendants may address any questions they have regarding the weight of the evidence on cross-examination.

⁷⁹ *Id.* at 441:21- 442:5.

⁸⁰ *See Poust*, 998 F.Supp. at 497.

⁸¹ *Heller*, 167 F.3d at 157 (internal citations omitted).

E. Dr. John Godleski's Opinions Are Not Dispositive to the Admission Of Dr. Wolf's Opinions.

Dr. Godleski conducted a pathologic evaluation of the tissue removed from Ms. Gallardo and Ms. Judkins and discovered damning evidence: both women had talc particles, talc fibers, and/or asbestos in their pathologic tissue. Because Dr. Wolf typically reviews and considers pathology in her medical practice⁸², she reviewed these findings and included them on the materials he considered. While Dr. Wolf did not consider these findings a requirement for her causation opinions, they were informative, as they add strength to her opinion that talc causes ovarian cancer.⁸³ Even if Dr. Wolf had not been provided with any of Dr. Godleski's reports, she would still be able to conclude that talcum powder use contributed to the risk of ovarian cancer in these women.⁸⁴

Therefore, while helpful, Dr. Wolf's opinions do not rely on Dr. Godleski's report, and thus Dr. Godleski's opinions are not dispositive to the issue of whether Dr. Wolf's testimony should be excluded. To the extent Defendants argue that Dr. Godleski's opinions are unreliable or inadmissible, those arguments will be addressed in Plaintiffs' Steering Committee's Opposition to Defendants' Motion to Exclude the Opinions of Dr. John Godleski.

⁸² See Dep. of Wolf, Sept. 14, 2021, at 596:12-14.

⁸³ Dep. of Judith Wolf, M.D., Sept. 13, 2021, at 378:16-379:24, Dep. of Wolf, Sept. 14, 2021, at 594:16-597:6.

⁸⁴ *Id.*

V. CONCLUSION

For these reasons, Defendants' motion to exclude Dr. Wolf's case-specific opinions should be denied.

Respectfully submitted,

/s/ Michelle A. Parfitt

Michelle A. Parfitt
ASHCRAFT & GEREL, LLP
1825 K Street, NW, Suite 700
Washington, DC 20006
Tel: 202-783-6400
Fax: 202-416-6392
mparfitt@ashcraftlaw.com

/s/ P. Leigh O'Dell

P. Leigh O'Dell
BEASLEY, ALLEN, CROW, METHVIN,
PORTIS & MILES, P.C.
218 Commerce Street
Montgomery, AL 36104
Tel: 334-269-2343
Fax: 334-954-7555
Leigh.odell@beasleyallen.com
Plaintiffs' Co-Lead Counsel

/s/ Christopher M. Placitella

Christopher M. Placitella
COHEN, PLACITELLA & ROTH, P.C.
127 Maple Avenue
Red Bank, NJ 07701
Tel: 732-747-9003
Fax: 732-747-9004
cplacitella@cprlaw.com
Plaintiffs' Liaison Counsel

PLAINTIFFS' EXECUTIVE COMMITTEE:

Warren T. Burns
BURNS CHAREST LLP
500 North Akard Street, Suite 2810
Dallas, TX 75201
Tel: 469-904-4551
Fax: 469-444-5002
wburns@burnscharest.com

Richard Golomb
GOLOMB & HONIK, P.C.
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Tel: 215-985-9177
rgolomb@golombhonik.com

Hunter J. Shkolnik
NAPOLI SHKOLNIK PLLC
360 Lexington Avenue, 11th Floor
New York, NY 10017
Tel: 212-397-1000
hunter@napolilaw.com

PLAINTIFFS' STEERING COMMITTEE:

Laurence S. Berman
LEVIN, SEDRAN & BERMAN LLP
510 Walnut Street, Suite 500
Philadelphia, PA 19106
Tel: 215-592-1500
Fax: 215-592-4663
lberman@lfsblaw.com

Timothy G. Blood
BLOOD, HURST & O'REARDON,
LLP
701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619-338-1100
Fax: 619-338-1101
tblood@bholaw.com

Sindhu S. Daniel
BARON & BUDD, P.C.
3102 Oak Lawn Avenue, #1100
Dallas, TX 75219
Tel: 214-521-3605
Fax: 214-520-1181
sdaniel@baronbudd.com

Jeff S. Gibson
WAGNER REESE, LLP
11939 N. Meridian St.
Carmel, IN 46032
Tel: (317) 569-0000
Fax: (317) 569-8088
jgibson@wagnerreese.com

Kristie M. Hightower
LUNDY, LUNDY, SOILEAU & SOUTH,
LLP
501 Broad Street
Lake Charles, LA 70601
Tel: 337-439-0707

Daniel R. Lapinski
MOTLEY RICE LLC
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel: 856-667-0500
Fax: 856-667-5133

Fax: 337-439-1029
khightower@lundylawllp.com

dlapinski@motleyrice.com

Victoria Maniatis
SANDERS PHILLIPS GROSSMAN, LLC
100 Garden City Plaza, Suite 500
Garden City, NJ 11530
Tel: 516-640-3913
Fax: 516-741-0128
vmaniatis@thesandersfirm.com

Carmen S. Scott
MOTLEY RICE LLC
28 Bridgeside Boulevard
Mount Pleasant, SC 29464
Tel: 843-216-9162
Fax: 843-216-9450
cscott@motleyrice.com

Christopher V. Tisi
LEVIN PAPANTONIO
316 South Baylen St.
Pensacola, FL 32502
(850) 435-7000
ctisi@levinlaw.com